

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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CHR. HANSEN HMO GMBH,

Plaintiff,

v.

GLYCOSYN LLC,

Defendant.

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) C.A. No. 1:22-cv-11090  
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**DECLARATION OF WILLIAMS S. DIXON**

I, Williams S. Dixon, hereby declare and state as follows:

1. My name is Williams S. Dixon. I am an attorney in the law firm of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C. and am counsel to Defendant Glycosyn LLC in this matter. I provide this declaration in support of Glycosyn’s Initial Claim Construction Brief. I have personal knowledge of the facts stated in this declaration, and could testify to these facts if called as a witness.

2. On August 9, 2023, via email, Counsel for Glycosyn offered the following construction as a compromise for the term “[an] exogenous functional  $\beta$ -galactosidase gene,”: “a functional sequence of contiguous or non-contiguous DNA, originating outside the E. Coli bacterium, that encodes a working  $\beta$ -galactosidase enzyme.” On August 20, 2023, Counsel for Counterclaim-Defendants communicated that they did not agree to Glycosyn’s compromise construction and instead proposed that the parties agree to the ITC’s construction. On August 23, 2023, Glycosyn rejected this proposal.

3. Attached herein as **Exhibit 1** is a true and correct copy of U.S. Patent No. 9,970,018 B2, entitled “Biosynthesis of Human Milk Oligosaccharides in Engineered Bacteria” and issued on May 15, 2018.

4. Attached herein as **Exhibit 2** is a true and correct copy of excerpts from Lodish et al., *Molecular Cell Biology*, 6th ed. (2008).

5. Attached herein as **Exhibit 3** is a true and correct copy of Tien Nguyen, *Synthesizing Mother’s Milk*, Chemical & Engineering News, 26-29 (July 2, 2018).

6. Attached herein as **Exhibit 4** is a true and correct copy of excerpts from U.S. Patent No. 9,944,965 B2, entitled “Biosynthesis of Oligosaccharides” and issued on April 17, 2018.

7. Attached herein as **Exhibit 5** is a true and correct copy of the web page downloaded on August 23, 2023 from the National Human Genome Research Institute’s website at <https://www.genome.gov/genetics-glossary/Gene>.

8. Attached herein as **Exhibit 6** is a true and correct copy of the Cambridge Dictionary’s definition of “gene,” downloaded on August 23, 2023 from the Cambridge Dictionary website at <https://dictionary.cambridge.org/us/dictionary/english/gene>.

9. Attached herein as **Exhibit 7** is a true and correct copy of excerpts from the transcript for the October 16, 2018 Markman Hearing held in *Certain Human Milk Oligosaccharides and Methods of Producing the Same*, Inv. No. 337-TA-1120.

10. Attached herein as **Exhibit 8** is a true and correct copy of excerpts from Florian Baumgärtner et al., *Construction of Escherichia coli strains with chromosomally integrated expression cassettes for the synthesis of 2'-fucosyllactose*, 12 Microbial Cell Factories No. 40 (2013).

11. Attached herein as **Exhibit 9** is a true and correct copy of Lars Bode, *Human milk oligosaccharides: Every baby needs a sugar mama*, 22 GLYCOBIOLOGY No. 9, 1147-1162, (September 2012).

12. Attached herein as **Exhibit 10** is a true and correct copy of excerpts from Esther Castanys-Muñoz, et al., *2'-fucosyllactose: an abundant, genetically determined soluble glycan present in human milk*, 71 NUTRITION REVIEWS No. 12, 773-789 (2013).

13. Attached herein as **Exhibit 11** is a true and correct copy of Dorothy L. Ackerman, et al., *Human Milk Oligosaccharides Exhibit Antimicrobial and Antibiofilm Properties against Group B Streptococcus*, ACS INFECT. DIS., No. 3, 595-605 (2017)

14. Attached herein as **Exhibit 12** is a true and correct copy of excerpts from Giuseppe Puccio, et al., *Effects of Infant Formula With Human Milk Oligosaccharides on Growth and Morbidity: A Randomized Multicenter Trial*, 64 JPGN No. 4, 624-631 (April 2017).

15. Attached herein as **Exhibit 13** is a true and correct copy of excerpts from GRAS Notice GRN No. 735 filed by Glycosyn, LLC and Friesland Campina Domo B.V. with U.S. Food and Drug Administration.

16. Attached herein as **Exhibit 14** is a true and correct copy of a web page downloaded on October 9, 2018 from the National Library of Medicine's PubChem database at <https://pubchem.ncbi.nlm.nih.gov/compound/170484#section=Chemical-and-Physical-Properties>.

17. Attached herein as **Exhibit 15** is a true and correct copy of an article by Sandeep Ravindran posted to the International Milk Genomics Consortium titled "Producing Human Milk Sugars for Use in Formula" and dated October 2015.

18. Attached herein as **Exhibit 16** is a true and correct copy of excerpts from Lars Bode, *Overcoming the limited availability of human milk oligosaccharides: challenges and opportunities for research and application*, 74 NUTRITION REVIEWS No. 10, 635-644 (October 2016).

19. Attached herein as **Exhibit 17** is a true and correct copy of excerpts from the Wikipedia page for “DNA” (<https://en.wikipedia.org/wiki/DNA>) downloaded on November 20, 2018.

20. Attached herein as **Exhibit 18** is a true and correct copy of excerpts from the Wikipedia page for “Gene” (<https://en.wikipedia.org/wiki/Gene>), downloaded on November 20, 2018.

21. Attached herein as **Exhibit 19** is a true and correct copy of excerpts from the Wikipedia page for “Gene expression” ([https://en.wikipedia.org/wiki/Gene\\_expression#Transcription](https://en.wikipedia.org/wiki/Gene_expression#Transcription)), downloaded on November 20, 2018.

22. Attached herein as **Exhibit 20** is a true and correct copy of excerpts from the Wikipedia page for “Protein” ([https://en.wikipedia.org/wiki/Protein#Cellular\\_functions](https://en.wikipedia.org/wiki/Protein#Cellular_functions)), downloaded on November 20, 2018.

23. Attached herein as **Exhibit 21** is a true and correct copy of excerpts from the Wikipedia page for “Enzyme” (<https://en.wikipedia.org/wiki/Enzyme>), downloaded on November 20, 2018.

24. Attached herein as **Exhibit 22** is a true and correct copy of the Wikipedia page for “Beta-galactosidase” ([https://en.wikipedia.org/wiki/Beta-galactosidase#Properties\\_and\\_functions](https://en.wikipedia.org/wiki/Beta-galactosidase#Properties_and_functions)), downloaded on November 19, 2018.

25. Attached herein as **Exhibit 23** is a true and correct copy of the Wikipedia page for “Fucosyltransferase” (<https://en.wikipedia.org/wiki/Fucosyltransferase>), downloaded on November 20, 2018.

26. Attached herein as **Exhibit 24** is a true and correct copy of the Wikipedia page for “Enzyme unit” ([https://en.wikipedia.org/wiki/Enzyme\\_unit](https://en.wikipedia.org/wiki/Enzyme_unit)), downloaded on November 20, 2018.

27. Attached herein as **Exhibit 25** is a true and correct copy of the Wikipedia page for “Biological engineering” ([https://en.wikipedia.org/wiki/Biological\\_engineering](https://en.wikipedia.org/wiki/Biological_engineering)), downloaded on November 20, 2018.

28. Attached herein as **Exhibit 26** is a true and correct copy of excerpts from the Wikipedia page for “Prokaryote” (<https://en.wikipedia.org/wiki/Prokaryote>), downloaded on November 20, 2018.

29. Attached herein as **Exhibit 27** is a true and correct copy of excerpts from the Wikipedia page for “Plasmid” (<https://en.wikipedia.org/wiki/Plasmid>), downloaded on November 20, 2018.

30. Attached herein as **Exhibit 28** is a true and correct copy of the Wikipedia page for “Molecular cloning” ([https://en.wikipedia.org/wiki/Molecular\\_cloning](https://en.wikipedia.org/wiki/Molecular_cloning)), downloaded on November 20, 2018.

31. Attached herein as **Exhibit 29** is a true and correct copy of excerpts of the Wikipedia page for “Recombinant DNA” ([https://en.wikipedia.org/wiki/Recombinant\\_DNA#Properties\\_of\\_organisms\\_containing\\_recombinant\\_DNA](https://en.wikipedia.org/wiki/Recombinant_DNA#Properties_of_organisms_containing_recombinant_DNA)), downloaded on November 20, 2018.

32. Attached herein as **Exhibit 30** is a true and correct copy of the Wikipedia page for “Industrial fermentation”

([https://en.wikipedia.org/wiki/Industrialfermentation#Fermentation\\_medium](https://en.wikipedia.org/wiki/Industrialfermentation#Fermentation_medium)), downloaded on November 20, 2018.

33. Attached herein as **Exhibit 31** is a true and correct copy of the Wikipedia page for “Protein purification” ([https://en.wikipedia.org/wiki/Protein\\_purification#Preliminary\\_steps](https://en.wikipedia.org/wiki/Protein_purification#Preliminary_steps)), downloaded on November 20, 2018.

34. Attached herein as **Exhibit 32** is a true and correct copy of an excerpt from Miller, J.H., Experiments in Molecular Genetics (Cold Spring Harbor Lab. 1972).

35. Attached herein as **Exhibit 33** is a true and correct copy of the Declaration of Dr. Kristala L. Jones Prather in Support of Complainant Glycosyn LLC’s Initial Claim Construction Brief and Appendices A and B thereto.

I declare under penalty of perjury under the laws of the United States of America that to the best of my knowledge the foregoing is true and correct.

Executed in Boston, Massachusetts on this 24<sup>th</sup> day of August, 2023.

/s/ Williams S. Dixon  
Williams S. Dixon

**CERTIFICATE OF SERVICE**

I certify that the above document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the NEF and paper copies will be sent to those indicated as non registered participants on August 24, 2023.

/s/ Williams S. Dixon  
Williams S. Dixon